K061276
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

1. SUBMITTER INFORMATION

a. Company Name:	USGI Medical
b. Company Address:	1140 Calle Cordillera San Clemente, CA 92673
c. Telephone: Fax:	(949) 369-3890 (949) 369-3891
d. Contact Person:	Mary Lou Mooney Vice President of Clinical, Regulatory & Quality
e. Date Summary Prepared:	May 5, 2006

2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	g-Cath™ Tissue Anchor Delivery Catheter g-Prox™ Endoscopic Grasper
b. Common Name:	PET Suture Implantable staple Grasper
c. Classification Name:	Suture, PET; 878.5000 (GAT) Implantable Staple; 878.4750 (GDW) Gynecologic laparoscope and accessories; 884.1720 (HET)

3. IDENTIFICATION OF PREDICATE DEVICES

Polyester Non-absorbable Surgical Sutures	Genzyme BioSurgery (K021019)
Coil Fixation Device	Onux Medical (K023372)

EndoANCHOR Fixation Device	Ethicon Endo-Surgery (K013749)
EndoPATH Tissue Grasper	Ethicon Endo-Surgery (K930933)
FG Grasping Forcep	Olympus America (K962474)

4. DESCRIPTION OF THE DEVICE

The g-Prox Endoscopic Grasper is a sterile, single patient use device used for tissue grasping and mobilization. It is also used as an accessory to the g-Cath Tissue Anchor Delivery Catheter for placement of tissue anchors for soft tissue approximation in minimally invasive gastroenterology procedures. A nitinol/polyester tissue anchor pair is deployed through the g-Cath Tissue Anchor Delivery Catheter lumen and compressed to approximate soft tissue. Anchor tensile strength meets USP for a size 4-0 nonabsorbable suture. The anchor does not meet USP for diameter and is oversized by 100% compared to a 4-0 nonabsorbable suture.

5. STATEMENT OF INTENDED USE

The g-Prox Endoscopic Grasper is intended for use in minimally invasive procedures to facilitate tissue grasping and mobilization.

The g-Cath Tissue Anchor Delivery Catheter is intended for soft tissue approximation in minimally invasive gastroenterology procedures.

6. COMPARISON WITH PREDICATE DEVICES

The g-Prox Endoscopic Grasper is comparable to the predicate devices in terms of intended use, technology, design and materials. The g-Cath Tissue Anchor Delivery Catheter is similar to the predicate devices in that it is indicated for soft tissue approximation in minimally invasive gastroenterology procedures; however this device deploys a tissue anchor pair made of nitinol and polyester.

Preclinical testing was performed to ensure the devices perform as intended when used according to their instructions for use. Bench and animal testing demonstrated satisfactory performance of the g-Prox Endoscopic Grasper and g-Cath Tissue Anchor Delivery Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

USGI Medical
% Ms. Mary Lou Mooney
Vice President of Clinical, Regulatory
& Quality
1140 Calle Cordillera
San Clemente, California 92673

DEC - 6 2006

Re: K061276
Trade/Device Name: g-Cath Tissue Anchor Delivery Catheter
g-Prox Endoscopic Grasper
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT, GDW, HET
Dated: November 10, 2006
Received: November 13, 2006

Dear Ms. Mooney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

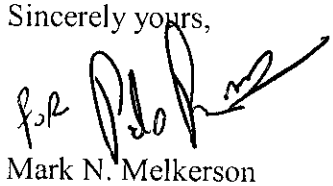
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K061276

Device Name: g-Cath Tissue Anchor Delivery Catheter

Indications For Use:

The g-Cath Tissue Anchor Delivery Catheter is intended for approximation of soft tissue in minimally invasive gastroenterology procedures

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061276

Indications for Use

510(k) Number (if known): K061276

Device Name: g-Prox Endoscopic Grasper

Indications For Use:

The g-Prox Endoscopic Grasper is intended for use in minimally invasive procedures to facilitate tissue grasping and mobilization.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
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